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MAR 4 2003

Arnold S. Milowsky
American Home Products Corporation
Egon Berg
One Campus Drive
Parsippany NJ 07054

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,626,538

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,626,538, which claims the human drug product Sonata® (zalepon), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,810 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 1,810 days.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of January 25, 2002 (67 Fed. Reg. 3723). Under 35 U.S.C. § 156(c):

Period of Extension = ½ (Testing Phase) + Approval Phase
= ½ (2435) + 592[1]
= 1,810 (4.96 years)

Since the regulatory review period began May 2, 1991, before the patent issued (December 2, 1986), the entire regulatory review period has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.: 4,626,538

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[1]It is noted that applicant, in determining the patent term extension, included time related to Drug Enforcement Agency activities. Regulatory activities that may be required by the DEA are not part of the regulatory review period upon which patent term extension may be based. (Unimed Inc. v. Quigg, 888 F.2d 826, 828; 12 USPQ2d 1644, 1646 (Fed. Cir. 1989)(The "Patent Term Restoration Act takes into account only the regulatory review carried out by the FDA and no other government obstacles to marketing new drugs."))

Granted:	December 2, 1986
Original Expiration Date[2]:	June 23, 2003
Applicant:	John P. Dusza, et al.
Owner of Record:	WYETH[3]
Title:	[7-(3-Disubstituted Amino)phenyl]pyrazolo(1,5-a)pyrimidines
Classification:	514/258
Product Trade Name:	Sonata® (zalepon)
Term Extended:	1,810 days
Expiration Date:	June 6, 2008

Any correspondence with respect to this matter should be addressed as follows:

By mail: Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231

By FAX: (703) 872-9411
Attn: Office of Patent Legal Administration

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: David T. Read
Acting Director Health Assessment Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

RE: Sonata®
FDA Docket No.: 00E-1234

[2]Subject to the provisions of 35 U.S.C. § 41(b).

[3]This is according to the change of name recorded at Reel 012828, Frame 0928.